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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,703	07/17/2003	Patrick L. Soderlund	73104-289802	1523

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Paul W. Busse  
FAEGRE & BENSON LLP  
2200 Wells Fargo Center  
90 South Seventh Street  
Minneapolis, MN 55402-3901

EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/621,703	<b>Applicant(s)</b> SODERLUND ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-24 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/17/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of power of attorney and response to Notice to File

Missing Parts filed 10/06/2003 and IDS filed 10/17/2003. Claims 1-24 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lidocaine, does not reasonably provide enablement for all local anesthetics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention
- 2) State of prior art
- 3) The predictability or lack thereof in the art
- 4) Amount of direction and guidance present
- 5) The presence or absence of working Examples
- 6) Breadth of the claims
- 7) Quantity of experimentation needed

#### **1) Nature of the invention**

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The nature of the invention is a sprayable homogeneous topical composition that is a solution having a) one or more local anesthetic agents, b) penetration enhancer, c) anhydrous volatile solvent and d) water.

## 2) State of the prior art

The prior art recognizes the following as local anesthetics, namely:

- a) the amino esters --- Benzocaine, Chloroprocaine, Cocaine, Procaine;
- b) the amino amides --- Bupivacaine, Levobupivacaine, Lidocaine, Mepivacaine, Prilocaine, Ropivacaine; and
- c) combinations such as lidocaine/prilocaine (EMLA).

## 3) The predictability or lack thereof in the art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific guidance is required to enable the artisan to practice the full scope of the claimed invention.

In the instant case, the scope of the claimed invention spans all local anesthetics, those known and those yet to be synthesized.

## 4) Amount of direction and guidance present

The direction and guidance provided is limited to lidocaine and not to the array of local anesthetics. The local anesthetics recited in claim 3 and disclosed at page 6, beginning with line 28 and ending at page 7 at line 15 represent an invitation to experiment. And because, the pharmaceutical art though having high level of skill in the area of producing local anesthetics is still unpredictable. It will require undue experimentation by the artisan to make solutions of all local anesthetic in all known and yet to be discovered volatile solvents and penetration enhancers

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that would be commensurate with the scope of the claims 1 and 15. The quantity of experimentation needed is undue experimentation.

5) The presence or absence of working Examples

The working examples are limited to lidocaine, ethanol and isopropyl palmitate. The working examples do not correlate with the scope of the claims.

6) Breadth of the claims

The claims are directed to all local anesthetics, all penetration enhancers and large pool of volatile solvents. The specification does not inform the public of the limits of the monopoly asserted at the time of filing. Ethanol is the only volatile solvent that is disclosed.

7) Quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to determine how many of the local anesthetics from the various local anesthetics can be formulated as solution with any volatile solvent and any penetration enhancers. The working examples are limited to lidocaine (local anesthetic), ethanol (volatile solvent and isopropyl palmitate (penetration enhancer).

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test and use the scope of the claimed invention encompassed in instant claims, with no assurance of success. The specification further fails to teach how to use the invention.

This rejection can be overcome by moving claim 3 into claims 1 and 15, by moving claim 6 into claims 1 and 15 and specifically reciting ethanol in the claims 1 and 15.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 depends on itself and the claims 16 and 17 are thus vague and confusing.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3, 4, 6-9 and 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Castillo (US 6,894,078).

Castillo discloses homogenous solution comprising topical anesthetic, volatile solvent and penetrating enhancer (abstract). One embodiment of the Castillo has 3-40% lidocaine as the anesthetics, 40-60% alcohol, 0.5 to 2% thickener, and 0.5 to 1.5% emulsifier and from about 20-40% water and lipophilic base (column 4, lines 38-50). The emulsifiers meet the limitation of the penetrating enhancer; the 40-60% of lidocaine meets the limitation of the amount of the anesthetic and of the specific anesthetic, lidocaine in claims 1, 3, 4, 18, 19; 20 % water meets the upper limit of water present in the instant composition in claim 1. Specific penetration

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enhancers namely esters such as isopropyl myristate, isopropyl palmitate, capric/caprylic triglycerides meeting the limitations of claims 6 and 7 are listed in column 5, lines 54-67. The % amount of the alcohol meets the limitation of the alcohol in claims 1, 8, 15, 18 and 19. Dibucaine, benzocaine, tetracaine, prilocaine, etidocaine, mepivacaine, and bupivacaine are other topical anesthetic that are used in the formulation of Castillo (column 6, lines 45-51).

Instant claims 11-14 recite the properties/characteristic of the composition. The amount of water that is less than 10% as is recited in claims 15, 18 and 19 has not been demonstrated to provide unexpected result to the composition.

Castillo meets the limitations of the designated claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claims 2, 5, 15 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castillo (US 6,894,078) in view of Stone (US 4,322,020).

Castillo is described above. The % anesthetic in claim 2 is 35% while the prior art discloses lower limit % of 40%. However, there is no demonstration in applicant's specification that a % anesthetic of 35% provides unexpected result to the anesthetic composition. Furthermore, a 10% water recited in claims 15, 18 and 19 has not been shown by applicant's specification to provide unusual result to the anesthetic composition. The composition of Castillo is applied to the skin, and thus to the mucosa. However, Castillo does not disclose using a spray pump for application of the anesthetic to the skin. But Stone discloses the use of spray pump for application of composition comprising benzocaine, water, ethanol and polyethylene glycol monolaurate (Example 1; abstract and Figures 1-3). Ethanol is used with benzocaine in Example 1 of Stone.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the composition of Castillo to the skin and be motivated to use a pump spray with the expectation that using a pump spray could be used for application in any direction.

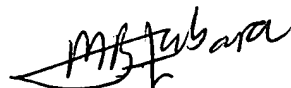
10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Blessing Fubara  
Patent Examiner  
Tech. Center 1600